K052018

NOV - 4 2005

Miltex
Redefining Excellence

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510(k) Summary [as required by 21 CFR §807.92(c)]

510(k) Owner's Name and Address: Miltex, Inc.
589 Davies Drive
York, PA 17402

Contact Information: Telephone 717-840-9335, Fax 717-840-9347
Contact Person: Lee Zagar, Vice President Quality Assurance and Regulatory Affairs
Date Summary Prepared: September 12, 2005

Device Trade Name: Miltex Ligating Clip.
Device Common Name: Ligating Clip.
Classification Name: *Clip, Vascular* (21 CFR 870.3250, Product Code DSS)

Predicate Device: Horizon™ Ligation System by Week Closure Systems- K982313

Device Description: The Miltex Ligating Clip is constructed exclusively of CP Grade 1 titanium wire having a heart-shaped cross-section. The clip is chevron-shaped. The inside (tissue-engaging) surfaces of the clip legs have a longitudinal groove intersected by a number of angled transverse grooves. The longitudinal grooves do not extend fully to the distal ends of the legs, but leave distal flat surfaces at the ends of the legs. When the clip is closed, tissue will fill in the grooves, providing secure retention on the vessel. This feature also improves the occluding functions of the clip. The distal flat ends of the legs provide surfaces that will contact each other initially as the clip is closed. The contact of the distal flat surfaces will cause the legs to straighten in alignment with each other, thereby minimizing the possibility of scissoring. Clips are available in 4 sizes: small, medium, medium-large, and large. The clips are packaged six per disposable cartridge holder. The clips and cartridge holder are supplied sterile. Cartridge holders are color-coded using the industry standard color-coding system.

Intended Use: The Miltex Ligating Clip is an extra-vascular, implanted device intended to occlude by compression blood flow within small, non-intracranial vessels. The clip is available in several sizes and the practitioner chooses the size of clip to fit the procedure, insuring that the tissue to be occluded fits completely within the clip.

Technological Characteristics: The Miltex Ligating Clip has the same technological characteristics as the predicate device. The clip is composed of the same titanium material as the predicate device. In shape, the Clip is the same as the predicate device. When closed, the Clip is virtually identical in size to the predicate device. The disposable holder is a plastic equivalent to the predicate device's.

Performance Data: When used with the appropriate clip applier, the Miltex Ligating Clip functions in the same manner as the predicate device to occlude blood vessels. The clip is biocompatible, is not endo-toxic, and is supplied sterile.

Conclusion:
Because the Miltex Ligating Clip is composed of the same material, has the same design and dimensions, and is supplied sterile, it is as safe, as effective, and performs as well as the Horizon Ligation System (K982313).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Charles Weaver
Regulatory Affairs Coordinator
Miltex, Inc.
589 Davies Drive
York, Pennsylvania 17402

Re: K052018
Trade/Device Name: Miltex Ligating Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: October 12, 2005
Received: October 13, 2005

Dear Mr. Weaver:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052018

Device Name: Miltex Ligating Clip

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K052018